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MAR 2 3 2000

510(k) Summary
Bionx Implants Inc.
SmartWedge ACL™

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Bluebell, PA 19422

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President and Chief Executive Officer
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Bionx Implants Ltd.
Tuija Annala
Quality Manager
P.O.Box 3
FIN-33721 Tampere
Finland, Europe
Phone: 358-3-316 5679
Facsimile: 358-3-316 5688

Date prepared: February 4th, 2000

Name of the device:

A.	Trade or Proprietary Name:	SmartWedge ACL™
B.	Common Name:	Bioabsorbable Interference Fastener
C.	Classification Name:	Biodegradable fixation fastener, bone and soft tissue
D.	Device Product Code:	HWC and MAI

Predicate Devices:
Bionx Implants Inc. SmartScrew ACL™ (K993073)

Intended Use:
The SmartWedge ACL™ is intended for use in interference fixation of bone-patellar tendon – bone and soft tissue grafts in anterior and posterior cruciate ligament reconstructions.

Device Description:

The SmartWedge ACL™ is a tapered wedge with machined profile on upper and lower sides. SmartWedge ACL™ is provided with three different diameter, 6.0, 7.0 and 8.0mm and with two lengths, 23 and 28mm and it is made of poly-L/D-lactide copolymer.

The SmartWedge ACL™ has the following similarities to the cleared SmartScrew ACL™ (K993073):

- has the same indicated use
- use the same operating principle
- is manufactured by same machinery
- is manufactured of the same raw material
- is packaged and sterilized using the same materials and processes
- has the same shelf life

Substantial Equivalence:

The SmartWedge ACL™ has the same intended use, principles of operation and technological characteristics than predicate device.

In summary, the SmartWedge ACL™ is, in our opinion, substantially equivalent to the predicate devices. Furthermore, the minor technological differences between the SmartWedge ACL™ and the predicate device do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2000

Mrs. Tuija Annala
Bionx Implants, LTD.
P.O. Box 3
FIN-33721 Tampere
Finland

Re: K000616
Trade Name: SmartWedge™ ACL Bioresorbable Interference Screw
Regulatory Class: II
Product Code: MAI and HWC
Dated: February 8, 2000
Received: February 24, 2000

Dear Mrs. Annala:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K000616

Device Name: SmartWedge ACL™

Indications for Use:

The SmartWedge ACL™ is intended for use in interference fixation of bone-patellar tendon – bone and soft tissue grafts in anterior and posterior cruciate ligament reconstructions in the presence of appropriate immobilization / controlled mobilization.

The SmartWedge ACL™ is not intended for use in and is contraindicated for 1) cruciate ligament reconstructions, which would not be appropriate for fixation with metallic screws, 2) Insufficient quality and quantity of bone for attachment of graft, 3) Blood supply limitations and/or previous infections, which could retard healing, 4) Patients with active or potential sepsis or infection and 5) Conditions which tend to limit the patients ability or willingness to restrict activities or follow direction during the healing and rehabilition period.

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000616